

# Notice of Allowability

Application No.

09/509,734

Examiner

David A. Saunders, PhD

Applicant(s)

ITESCU, SILVIU

Art Unit

1644

## -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to amendment of 7/27/05.
2. ☒ The allowed claim(s) is/are 1-7 and 19.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All b) ☐ Some\* c) ☐ None of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
  - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
    - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
  - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

## Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date \_\_\_\_\_
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_

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Amendment of 7/27/05 has been entered. Claims 1-7 and 19 are pending. Claims 1-7 and 19 are under examination. The amendment has entered no new matter.

A sua sponte examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

An abstract has been provided as follows:

On the attached face page sheet from PCT/US98/20887, use the Abstract of section (57) as the abstract of the instant application.

This amendment fulfills the requirement to provide an abstract on a separate sheet, as set forth in the Office actions of 5/24/02 and 8/13/03.

The following is an examiner's statement of reasons for allowance:

The amendment has overcome previously stated issues as follows:

The rejection of claim(s) 1-7 under 35 USC 112, 2<sup>nd</sup> paragraph. Examiner concurs that the disclosed test for T-lymphocyte activation does not depend upon the use of a particular antigen. See page 3, lines 16-17; page 6, lines 23-26; page 9, line 29-page 10, line 10; page 18, lines 15-20; and page 23, lines 8-20 indicating that IL-2, IL-15 or donor derived antigens may be used.

The rejection of claim(s) 7 under 35 USC 112, 2<sup>nd</sup> paragraph, due to the amendment of claim 7.

The rejection of claims 1-7 under 35 USC 112, 1st paragraph. It is noted that applicant has exemplified activation of T-cell growth with a nonspecific agent (IL-2). See page 3, lines 16-17; page 6, lines 23-26; page 9, line 29-page 10, line 10; page 18, lines 15-20; and page 23, lines 8-20. The examiner concurs that step c) of claim 1 provides for a test of immunological reactions specifically directed against Class II antigens.

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Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

The drawings filed on 6/14/00 have been approved by the draftsman. The indication of an objection thereto on Form PTO-326 mailed 5/24/02 was in error.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Saunders, PhD whose telephone number is 571-272-0849. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Typed 10/12/05 DAS

  
DAVID SAUNDERS  
PRIMARY EXAMINER  
ART UNIT 182-1644

PCT

WORLD INTELLECTUAL PROPERTY ORGANIZATION  
International Bureau



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

<b>(51) International Patent Classification <sup>6</sup> :</b> <b>C12Q 1/04, G01N 33/50</b>	<b>A1</b>	<b>(11) International Publication Number:</b> <b>WO 99/18231</b> <b>(43) International Publication Date:</b> 15 April 1999 (15.04.99)
<b>(21) International Application Number:</b> PCT/US98/20887 <b>(22) International Filing Date:</b> 2 October 1998 (02.10.98)  <b>(30) Priority Data:</b> 60/060,992 3 October 1997 (03.10.97) US 60/090,153 22 June 1998 (22.06.98) US  <b>(71) Applicant (for all designated States except US):</b> THE TRUSTEES OF COLUMBIA UNIVERSITY IN THE CITY OF NEW YORK [US/US]; 116th Street and Broadway, New York, NY 10027 (US).  <b>(72) Inventor; and</b> <b>(75) Inventor/Applicant (for US only):</b> ITESCU, Silviu [AU/US]; Apartment 12E, 279 E. 44th Street, New York, NY 10017 (US).  <b>(74) Agents:</b> TANG, Henry et al.; Baker & Botts, LLP, 30 Rockefeller Plaza, New York, NY 10112-0228 (US).		<b>(81) Designated States:</b> AU, CA, US, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).  <b>Published</b> With international search report.
<b>(54) Title:</b> METHOD FOR PREDICTING TRANSPLANT REJECTION  <b>(57) Abstract</b>  The present invention relates to a method for predicting whether or not transplant recipients are likely to reject tissue allografts. It is based, at least in part, on the discovery that, based on analysis of three immunologic factors, cardiac transplant recipients could be classified into risk categories for progression to high-grade rejection. The present invention, by enabling a determination of the risk for high-risk rejection in a transplant patient, reduces unnecessary diagnostic and therapeutic procedures in low risk patients and clinical intervention in patients who would most benefit.		

Part of Paper No. 101305